Trinity Delta

Scancell

Update

Heading into important 2024 clinical catalysts

31 January 2024

Scancell has a number of important clinical catalysts upcoming in 2024 for its lead cancer vaccines, which are the strategic focus. Readouts include further Phase II data for SCIB1 in advanced skin cancer, first clinical data with second-generation iSCIB1+, and key CPI combination data for Modi-1 in multiple solid tumours. Commercial prospects for these will likely be maximised through partnerships, and positive data could catalyse interest and discussions, in our view. In addition, Scancell's antibody platforms, GlyMab and AvidiMab, provide attractive out-licensing opportunities. Cash has been boosted through the December fundraise, with a runway now comfortably into late 2025. Our updated Scancell rNPV valuation is £304m, or 33p per share.

Year-end: April 30	2022	2023	2024E	2025E
Revenues (£m)	0.0	5.3	0.0	0.0
Adj. PBT (£m)	(7.2)	(14.3)	(11.8)	(15.3)
Net Income (£m)	(4.6)	(11.9)	(10.2)	(13.8)
EPS (p)	(0.56)	(1.46)	(1.16)	(1.49)
Cash (£m)	28.7	19.9	17.8	7.5
EBITDA (£m)	(12.6)	(11.0)	(14.7)	(13.5)

Source: Trinity Delta Note: Adjusted numbers exclude exceptionals

- **Further SCIB1 data expected Q324** Data from the second stage of the Phase II SCOPE study of SCIB1 in combination with checkpoint inhibitors (CPIs) in advanced melanoma are now expected in Q324, based on current recruitment. The aim is to show that the SCIB1 combination can exceed currently achievable response rates (c 50%). Following positive first stage data, where the objective response rate was 85%, this second stage has a 90% probability of success. Initiation of a third study cohort with the improved second-generation iSCIB1+, which is more potent and capable of addressing all melanoma patients, was recently approved and is expected to start in Q124 with first data in Q324. A potentially registrational adaptive Phase II/III trial is currently being planned, assuming Q324 data are positive.

- **Moditope platform continues to progress, with Modi-1 data expected 2024** The Phase I/II ModiFY trial of Modi-1 as monotherapy and in combination with CPIs in various challenging solid tumours is ongoing. A new cohort in renal cell carcinoma with double CPI therapy is also being added. Initial early signals of efficacy have already been observed in various monotherapy cohorts and further data are expected in 2024, with the CPI combination data particularly important.

- **Cash runway extends into late 2025** The £11.9m (gross) upsized placing and open offer completed in December 2023, coupled with existing cash, provides a cash runway into late 2025. This is beyond upcoming clinical data for SCIB1/iSCIB1+ and Modi-1 in 2024, and also provides flexibility to prepare future development plans. The runway could be extended further through the partnering or out-licensing of selected programmes from the GlyMab and AvidiMab antibody platforms.

- **Updated valuation of £304m, equivalent to 33p per share** Our valuation has been updated to reflect the passage of time, revised forecasts following FY23 and interim financial results, and incorporation of the December fundraise. These changes result in a valuation of £304m (from £300m), equivalent to 33p per share.

Price	11.30p
Market Cap	£104.8m
Enterprise Value	£92.6m
Shares in issue	927.8m
12 month range	7.59-21.49p
Free float	57.0%
Primary exchange	AIM London
Other exchanges	N/A
Sector	Healthcare
Company Code	SCLP.L
Corporate client	Yes

Company description

Scancell is a clinical-stage immuno-oncology specialist that has four broadly applicable technology platforms. Two are therapeutic vaccines, Moditope and ImmunoBody, and two are antibody based, GlyMab and AvidiMab.

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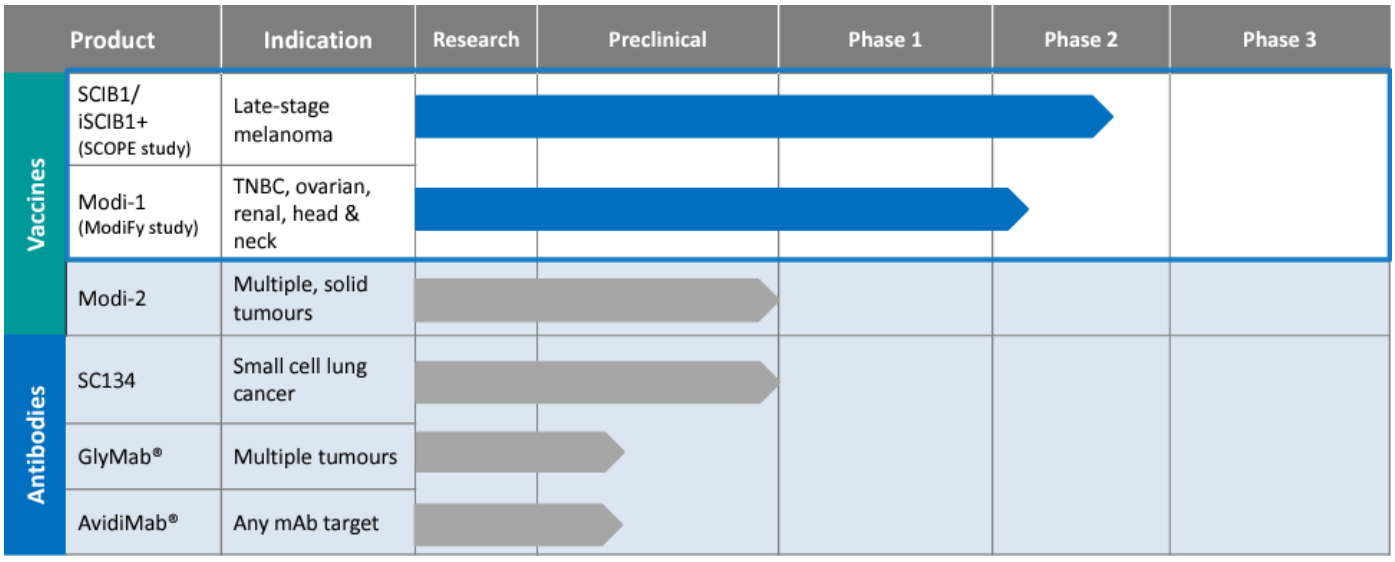
Scancell: multiple platforms and opportunities

Scancell is a clinical stage biotechnology company focused on the adaptive immune system, with four distinct technology platforms: two promising oncology vaccine platforms (Moditope and ImmunoBody), and two antibody technologies (GlyMab and AvidiMab). These have the potential to treat many solid cancers, either as monotherapy or in combination with other agents. Modi-1, the first Moditope programme, is progressing in a Phase I/II trial targeting hard-to-treat solid tumours, and further efficacy data, notably in combination regimens, are due during 2024. The lead ImmunoBody programme, currently SCIB1, has already demonstrated impressive response data in the ongoing Phase II study in metastatic melanoma, with a transition to the next-generation iSCIB1+ expected in coming months. The broad acting GlyMab antibodies are generating exciting preclinical data; a first partnering deal with antibody expert Genmab was executed in October 2022, and further deals are possible. AvidiMab technology could be increasingly employed to enhance avidity and potency. Our risk adjusted NPV valuation for Scancell is £304m, or 33p per share, with significant upside from multiple upcoming catalysts.

Four distinct platforms with broad applicability

Scancell has four distinct technology platforms that address oncology vaccines and antibodies: (1) **Moditope** vaccine effects are mediated via CD4 pathways; (2) **ImmunoBody** vaccines employ CD8 T cell pathways; (3) the **GlyMab** platform generates high affinity anti-glycan antibodies; and (4) **AvidiMab** can enhance the avidity of most antibodies. Scancell's pipeline is summarised in Exhibit 1 and more details on each platform are available in our February 2023 Outlook.

Exhibit 1: Scancell pipeline overview



Source: Scancell

Clinical data for focus programmes expected in 2024, with cash sufficient into 2025

The near-term focus is on progressing the clinical development of SCIB1/iSCIB1+ and Modi-1, with data for both expected during 2024. Meanwhile, for the GlyMab platform, the Genmab deal is an example of the partnering optionality, and we expect other programmes could also be partnered for future clinical development. The recent December £11.9m (gross) fundraise has provided Scancell with a runway into late 2025, beyond key near-term inflection points. We provide a summary of recent data and upcoming catalysts for the focus programmes below.

More SCIB1 data in Q324 following initial positive results

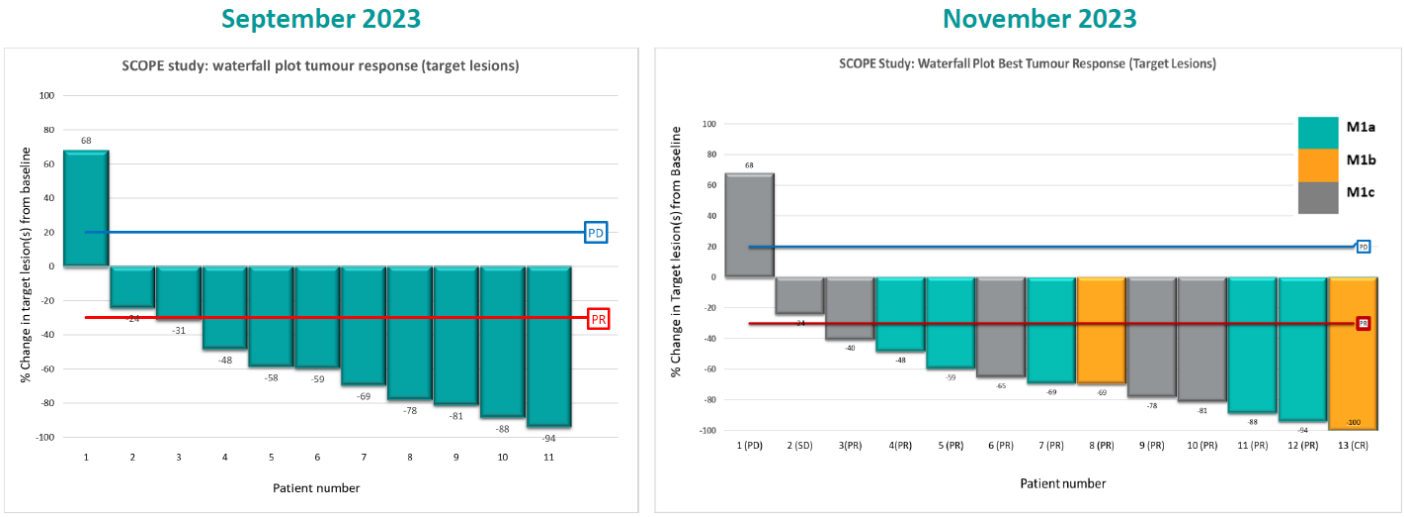
SCIB1 with doublet therapy could act synergistically to improve efficacy

The lead ImmunoBody programme is currently SCIB1, which is being developed for the treatment of advanced unresectable melanoma. The open label Phase II SCOPE study is ongoing, which is examining SCIB1 in combination with checkpoint inhibitor (CPI) doublet therapy, consisting of Yervoy (ipilimumab) plus Opdivo (nivolumab). Based on preclinical data which suggest a synergistic effect when SCIB1 is combined with a relevant CPI, the SCOPE study rationale is that such a combination could improve efficacy, based on the SCIB1 ImmunoBody vaccine priming an immune response against the tumour, with the CPI reducing the immune-suppressant effect seen in the tumour microenvironment.

Impressive 85% response rate achieved to date…

In September, initial top-line data from the first stage of the SCOPE trial demonstrated that SCIB1 plus doublet therapy achieved an objective response rate (ORR) of 82%, based on nine responses in 11 patients (September 2023 Lighthouse), with no increase in toxicity. At this timepoint, the tumour reduction at 13 weeks was 31-94%, with four patients reaching week 25 achieving 69-94%, and two patients at 37-weeks achieving 87-94%. In November, a further two responses were recorded (11 out of 13 patients), bringing the ORR to 85%. Importantly, this included one complete response, plus nine confirmed partial responses (waterfall plots shown in Exhibit 2).

Exhibit 2: SCOPE study initial results



Source: Scancell

…exceeding currently achievable outcomes with doublet therapy alone

The 85% ORR observed in SCOPE is higher than the planned study assumption of 70% for the SCIB1/doublet therapy combination (and the assumed 50% response rate for doublet therapy alone). As we have previously outlined (September 2023 Update), doublet therapy response rates are around 48-58%, which to date have been the highest observed in advanced melanoma.

Positive SCOPE data in Q324 could lead to the start of a registrational trial in H224

SCOPE is now in the second stage, and will recruit up to a total of 43 patients (including those already recruited in the first stage), with data now expected in Q324 based on the current recruitment rate. The aim is to achieve at least 27 responses in total to demonstrate SCIB1 can exceed currently achievable ORRs. The strength of the initial top-line data mean this second stage has a 90% probability of success. SCOPE will also transition in Q124 to the improved second-generation iSCIB1+ construct, which is enhanced with AvidiMab with first

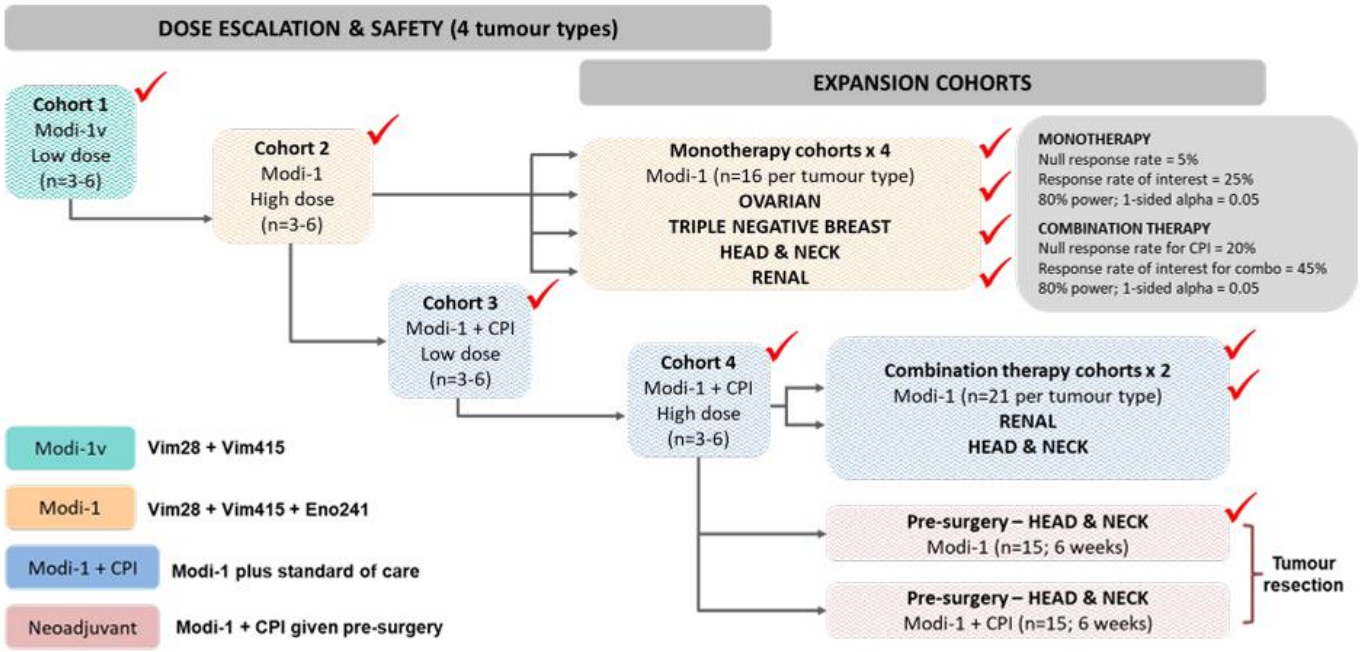
data expected Q324. This could broaden the target market by addressing 100% of melanoma patients, and is also more potent. A potentially registrational Phase II/III trial is currently being planned, assuming Q324 data are positive.

Modi-1 combination data in 2024 will be key

Phase I/II basket design to maximise understanding

The Phase I/II ModiFY study of Modi-1 is multi-cohort, adaptive trial, which has already completed the initial dose escalation and safety phase, and is ongoing in a number of specific expansion cohorts that explore Modi-1 in four different hard-to-treat solid tumours (triple-negative breast cancer (TNBC), ovarian cancer, head & neck cancer, and renal cancer) as monotherapy, in combination with CPIs, as well as in the neoadjuvant (pre-surgical) setting. A new cohort including renal cell carcinoma in combination with double CPI therapy (Yervoy+ Opdivo) is also being added. The trial design is in Exhibit 3.

Exhibit 3: Modi-1 Phase I/II clinical trial design



Source: Scancell Note: CPI = checkpoint inhibitor

Early monotherapy Modi-1 data are encouraging

Modi-1 was well tolerated at both low and high doses as monotherapy and in combination with a CPI in the initial dose escalation and safety phase. There has also been encouraging early efficacy as monotherapy in various hard-to-treat cancers, including head and neck, ovarian and breast cancer. Despite failing prior treatments, 60% of patients receiving Modi-1 achieved stable disease for at least eight weeks, and some patients experienced longer periods of stabilisation.

CPI combination data in 2024 will be key for Modi-1's clinical and commercial positioning

The combination of Modi-1 with CPIs could potentially improve these observed response rates, and data are expected during 2024. Recruitment is focused on Modi-1 in combination with a CPI in head & neck and renal cancers, and will now also include a new cohort in renal cell carcinoma in combination with double CPI therapy, and in the neoadjuvant (pre-surgery) setting in head & neck cancer. Together, these will provide supporting data for use of Modi-1 in combination with CPIs, particularly with double CPI treatment.

Valuation

Updated rNPV valuation of £304m, or 33p per share

We value Scancell as a classic drug discovery and development play, using a sum of the parts rNPV-based model for the key platforms, with each incorporating associated costs. These are summed together with cash. As is usual, we have rolled forwards our valuation in time, have updated for FY23 and interim results including cash, and have incorporated the £11.9m (gross) December fundraise. These result in a valuation of £304m (from £300m), which has been diluted to 33p per share (from prior 37p) owing to the increased number of shares issued as part of the fundraise. Our updated valuation is shown in Exhibit 4.

Exhibit 4: Sum of the parts rNPV-based valuation of Scancell

	NPV (£m)	Likelihood of success	rNPV (£m)	rNPV/ share (p)	rNPV/ share diluted (p)	Notes
Moditope platfom	1,234.1	12.5%	154.3	16.6	13.0	Peak sales: £3.5bn Royalties: 17.5% Launch year: 2029
ImmunoBody platfom	684.8	5%-10%	52.5	5.7	4.4	Peak sales: £2bn Royalties: 17.5% Launch year: 2029-2030 NB: includes SCIB1/iSCIB1+ at 10%
GlyMab TaG antibodies	1,398.9	3.5%-5%	50.2	5.4	4.2	Peak sales: £5bn Royalties: 17.5% Launch year: 2030 NB: includes Genmab deal at 5%
AvidiMab platfom	1,464.5	2.0%	29.3	3.2	2.5	Peak sales: £8.5bn Royalties: 8% Launch year: 2030
Cash	17.8		17.8	1.9	1.5	FY24 cash forecast
Total	**4,800.1**		**304.0**	**32.8**	**25.7**	

Source: Trinity Delta Note: Include a 12.5% discount factor, £/$ FX rate of 1.20, and 10% taxation from 2029 (UK patent box)

Greatest visibility on the vaccine platforms

Our ImmunoBody valuation combines a placeholder for the platform, where we assume peak sales of $1bn at 5% probability, and also includes a standalone valuation for SCIB1/iSCIB1+ at 10% probability (as it is more advanced in development) with peak sales of $1bn; SCIB1/iSCIB1+ is worth c £36m in rNPV, representing c 70% of the entire ImmunoBody valuation. We maintain a blended royalty rate of 17.5% for the product-based elements (apart from for the Genmab deal where we include more specific deal terms), reflecting the typical upfronts and progress milestones that could form part of any future partnering deals. For AvidiMab we use a more modest 8% blended rate, which reflects the lower relative value-add, but offset to a degree by a broader applicability.

Valuation based on conservative assumptions, with significant potential upside

The current limited visibility means we have adopted conservative assumptions, arguably overly so, regarding market sizes and growth rates, net pricing, adoption curves, and peak market penetration. This leaves the potential for future upside if progress materialises as management expects. There are a number of likely catalysts expected over the next 12-18 months, notably data for both SCIB1/iSCIB1+ and Modi-1, with successful outcomes likely leading to upward revisions to our valuation.

Financials

Genmab upfront received in FY23; no further near-term milestones are included in our financial forecasts

Scancell did not report any H124 revenues (6 months to 31 October 2023), whilst H123 revenues of £5.3m related entirely to the non-recurring $6m upfront received from partner Genmab for the October 2022 GlyMab deal (October 2022 Lighthouse), which was recognised in full at the time of the deal. Scancell is entitled to future potential development, regulatory and commercial milestones of up to $624m for development across all modalities, with $208m for each product, plus single digit royalties on net sales. Despite the potential for future milestones, either from Genmab or from new partnering agreements, we conservatively do not include any near-term significant income in our financial forecasts.

R&D spend reflects ongoing clinical progress

R&D spend in H124 increased to £5.7m (H123: £4.3m) reflecting clinical trial progression, notably the ModiFY and SCOPE trials, whilst G&A was largely unchanged at £2.4m (H123: £2.4m). These led to an operating loss of £8.1m (H123: £2.0m). Development beyond current trials will depend on clinical data, potential partnering interest, and sufficient resources being available to reach value inflection points. Hence for now our R&D spend forecasts, which are largely illustrative pending data and future plans, are based on current trials which will be completing. Therefore we forecast small declines from £11.6m in FY23 to £10.5m in FY24e and to £9.2m in FY25e. For G&A we forecast very modest rises from £5.0m in FY23 to £5.1m in FY24e and £5.2m in FY25e.

Convertible loan note accounting includes non-cash items

Financial income in H124 was £4.5m (H123: loss of £4.0m), which included a non-cash finance gain of £4.9m (H123: expense of £3.5m) for revaluation of the derivative financial liability relating to the convertible loan notes. Altogether, this plus other elements led to a net loss in H124 of £2.5m (H123: £5.0m).

Cash runway post the December fundraise extends into late 2025

Cash at end October was £13.1m (end April 2023: £19.9m) and in December Scancell successfully raised £11.9m (gross) via a capital raise consisting of: (1) £10.7m (gross) through an upsized placing to new and existing institutional shareholders; and (2) £1.2m (gross) through an Open Offer to qualifying shareholders. A total of 108.2m new shares were issued at 11p per share, representing a discount of 10.2% to the middle market closing price on 29 November 2023, before the raise was announced. According to our updated forecasts (Exhibit 5) and outlined above, this should be sufficient to fund operations into late 2025.

Exhibit 5: Summary of financials

Year-end: April 30	£'000s	2021	2022	2023	2024E	2025E
INCOME STATEMENT						
Revenues		**0**	**0**	**5,271**	**0**	**0**
Cost of goods sold		0	0	(525)	0	0
Gross Profit		**0**	**0**	**4,746**	**0**	**0**
R&D expenses		(6,406)	(9,477)	(11,645)	(10,485)	(9,201)
General and administrative expenses		(3,346)	(4,787)	(5,021)	(5,147)	(5,249)
Underlying operating profit		**(9,752)**	**(14,264)**	**(11,920)**	**(15,632)**	**(14,450)**
Other revenue/expenses		918	965	0	0	0
EBITDA		**(8,585)**	**(12,559)**	**(11,018)**	**(14,674)**	**(13,453)**
Operating Profit		**(8,834)**	**(13,299)**	**(11,920)**	**(15,632)**	**(14,450)**
Interest expense		(1,648)	(1,773)	(931)	(1,025)	(859)
Other financing costs/income		(6,323)	8,800	(1,453)	4,864	0
Profit Before Taxes		**(16,805)**	**(6,272)**	**(14,304)**	**(11,792)**	**(15,309)**
Adj. PBT		**(17,723)**	**(7,237)**	**(14,304)**	**(11,792)**	**(15,309)**
Current tax income		1,328	1,703	2,368	1,630	1,468
Cumulative preferred stock dividend		0	0	0	0	0
Net Income		**(15,477)**	**(4,569)**	**(11,936)**	**(10,162)**	**(13,841)**
EPS (p)		**(2.28)**	**(0.56)**	**(1.46)**	**(1.16)**	**(1.49)**
Adj. EPS (p)		**(2.42)**	**(0.68)**	**(1.46)**	**(1.16)**	**(1.49)**
DPS (p)		**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
Average no. of shares (m)		678.6	815.2	816.1	873.4	928.3
Gross margin		*N/A*	*N/A*	*90%*	*N/A*	*N/A*
BALANCE SHEET						
Current assets		**44,668**	**32,362**	**24,606**	**22,515**	**12,321**
Cash and cash equivalents		41,110	28,725	19,920	17,767	7,513
Accounts receivable		968	647	538	600	660
Inventories		0	0	0	0	0
Other current assets		2,590	2,990	4,148	4,148	4,148
Non-current assets		**4,390**	**6,159**	**5,664**	**4,907**	**4,110**
Property, plant & equipment		975	2,744	2,249	1,492	695
Other non-current assets		0	0	0	0	0
Current liabilities		**(2,295)**	**(2,452)**	**(3,276)**	**(1,900)**	**(30,449)**
Short-term debt		0	0	0	0	(27,617)
Accounts payable		(2,087)	(2,137)	(2,970)	(1,500)	(2,580)
Other current liabilities		(208)	(315)	(306)	(400)	(252)
Non-current liabilities		**(38,075)**	**(31,260)**	**(33,227)**	**(27,869)**	**0**
Long-term debt		(38,012)	(30,404)	(32,481)	(27,617)	0
Other non-current liabilities		(63)	(856)	(746)	(252)	0
Equity		**8,688**	**4,809**	**(6,233)**	**(2,347)**	**(14,018)**
Share capital		65,834	65,834	66,000	77,183	77,183
Other		(57,146)	(61,025)	(72,233)	(79,531)	(91,201)
CASH FLOW STATEMENTS						
Operating cash flow		**(7,803)**	**(10,193)**	**(8,140)**	**(13,038)**	**(9,922)**
Profit before tax		(16,805)	(6,272)	(14,304)	(11,792)	(15,309)
Non-cash adjustments		8,553	(5,597)	4,014	(2,081)	2,737
Change in working capital		449	372	940	(1,532)	1,020
Interest paid		0	0	0	0	0
Taxes paid		0	1,304	1,210	2,368	1,630
Investing cash flow		**(741)**	**(1,264)**	**81**	**101**	**69**
CAPEX on tangible assets		(744)	(1,268)	(203)	(200)	(200)
Other investing cash flows		3	4	284	301	269
Financing cash flow		**46,079**	**(928)**	**(746)**	**10,783**	**(400)**
Proceeds from equity		22,727	0	166	11,183	0
Increase in loans		23,506	0	0	0	0
Other financing cash flow		(154)	(928)	(912)	(400)	(400)
Net increase in cash		**37,535**	**(12,385)**	**(8,805)**	**(2,153)**	**(10,253)**
Cash at start of year		3,575	41,110	28,725	19,920	17,767
Cash at end of year		**41,110**	**28,725**	**19,920**	**17,767**	**7,513**
Net cash at end of year		3,098	(1,679)	(12,561)	(9,850)	(20,104)

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals.

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